

Appl. No. : 10/623,875  
Filed : July 21, 2003

### REMARKS

Prior to entry of the foregoing amendment, Claims 14 through 16, 18 through 20 and 37 through 43 stand pending in the present application. Claims 14, 19 and 20 have been amended herein, and new claims 44 through 56 have been added. All claims are believed to be in condition for allowance.

In the Office Action mailed January 26, 2007, Claims 19 and 20 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicant has amended Claim 19 herein to clarify that the portion of the aspiration lumen defined within a tubular wall having a plurality of folds therein is in the distal section of the catheter. Similarly, Claim 20 has been amended herein to clarify that the portion of the aspiration lumen which is defined within a stretchable tubular wall is in the distal section of the catheter. In view of the foregoing, Applicant respectfully submits that Claims 19 and 20 are in compliance with 35 U.S.C. § 112, second paragraph.

In the Office Action, independent Claim 14 and certain dependent claims were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,066,285 to Hillstead. Applicant respectfully submits that Hillstead fails to disclose or suggest each element of Claim 14, and requests that the outstanding rejection be withdrawn.

Hillstead discloses a three part system for providing vascular access. Referring to Figures 4 and 5, Hillstead illustrates the use of a dilator 28 coaxially removably positioned within an outer sheath 12. That two part assembly is percutaneously advanced into the target vessel. Thereafter, the dilator 28 is completely removed, and replaced by the catheter 36 seen in Figure 5. The distal end of the sheath 12 illustrated in Figure 4 appears to have a slight inward taper, which is gone in Figure 5<sup>1</sup>.

The three part vascular access system disclosed in Hillstead is profoundly different than Applicant's present claimed invention. Claim 14 recites a catheter having a proximal section with a fixed diameter, and a distal section moveable between a reduced inside diameter and an enlarged inside diameter. An axially moveable support is carried by the catheter, for controllably supporting the aspiration lumen against collapse when in the enlarged diameter.

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<sup>1</sup> The slight taper shown on the distal end of the sheath in Figure 4 which is absent in Figure 5 is inconsistent with the specification at Colum 5 Lines 10 through 20, where the sheath 12 is described as "very resistant to stretching, particularly in the radial direction".

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Contrary to the teaching of Hillstead, in which an inner dilator must be completely removed from the sheath in order to provide access through the sheath to permit introduction of the catheter, the distal section of Applicant's claimed catheter is enlarged or reduced by axial movement of the support wholly within the catheter (Claim 14 lines 14 through 17):

wherein the support is in a first proximal position within the catheter when the distal section is in the first inside diameter configuration and a second distal position within the catheter to support the distal section when the distal section is at the second inside diameter configuration.

Contrary to Applicant's claimed structure, Hillstead would be inoperative if the dilator 28 remained within the sheath 12 because there would be no way for the catheter 36 to be advanced through the sheath 12.

In view of the foregoing, Applicant respectfully requested that the rejection of independent Claim 14 and dependent Claims 18, 20 and 37 through 42 be withdrawn.

Claim 14 and certain dependent claims additionally stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,957,900 to Ouchi, with particular reference to Figure 14 and 15. However, Applicant respectfully submits that Ouchi fails to disclose or suggest each element in Claim 14.

Referring to Figure 14A in Ouchi, a flexible tube 911 is provided with an expandable and contractible mesh filter 914. See column 10, lines 5 through 20. The mesh filter 914 is attached to an axially moveable wire 13. Proximal retraction of the wire 13 pulls the mesh filter 914 inside the aspiration opening 912 for transluminal navigation. The purpose of this structure is to enable aspiration into aspiration opening 9, while the deployed mesh filter 914 blocks the introduction of debris into the aspiration opening 912. Importantly, the aspiration opening 912 does not change in diameter during operation of the Ouchi catheter.

In contrast, Applicant's claimed invention recites a structure in which a distal section of the catheter is provided with a reduced cross sectional dimension for navigation to a desired site, and a radially enlarged configuration to permit the introduction and removal of secondary devices, or to permit aspiration. These features are nowhere disclosed or suggested in Ouchi, and

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Applicant therefore requests that the Section 102 rejection of Claim 14 be withdrawn. Rejected Claims 18, 20 and 37 through 42 are all dependent from Claim 14, and are believed to be patentable for at least the same reasons as discussed in connection with Claim 14.

Claims 15, 16, 19 and 43 stand rejected under 35 U.S.C. § 103(a) as obvious over a combination of references. Each of these claims is dependent from independent Claim 14, and is believed to be patentable over the art of record for at least the reasons recited above.

Applicant has additionally added new independent Claim 44 and new dependent Claims 45 through 56. New Claims 44 through 56 are intended to be identical to currently pending Claims 14 through 16 and 18 through 43 as amended herein, with the exception that the preamble phrase "intracranial aspiration" in the previously pending claims has been replaced with "access".

Applicant respectfully submits that new Claims 44 through 56 are patentable for the same reason as the claims previously pending in this application. Applicant does not believe that the patentability of the previously pending claims was based upon the preamble "an intracranial aspiration catheter".

Written description support for the use of Applicant's invention as an access catheter more generally than intracranial aspiration may be found, among other places, in the Abstract of the invention:

Disclosed is an access catheter, having a distal segment which is moveable from a reduced outside diameter for positioning at a target site, and an enlarged outside diameter to create an enlarged internal working lumen. In one application, the catheter is configured for use as an intracranial aspiration catheter.

Applicant submits that all pending claims of the present application are in condition for allowance, and such action is earnestly solicited. If, however, any questions remain, the Examiner is cordially invited to contact the undersigned so that any such matter may be promptly resolved.

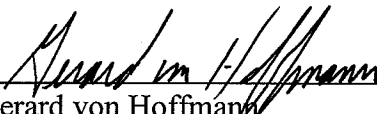
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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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